REMARKS

Status of the Claims

Claims 12, 14, 15, 17, 21, 22, 26 and 30 are pending in this application. Claim 12 is independent. Claim 12 has been amended to include the subject matter of claim 31 and thus, claim 31 has been cancelled. Also, claim 12 has been further defined to include the amount of galactomannan and the administrating amount of the composition, which are supported by at least the Examples (Tables 1, 5 and 7), page 12, lines 7-9, and page 13, line 4 of the specification. Thus, no new matter has been added.

Reconsideration of this application is respectfully requested.

Information Disclosure Citation

Applicants thank the Examiner for considering three Japanese references (JP 11-507406; JP 2002-531510; and JP 2003-534777) supplied with the Information Disclosure Statement filed November 2, 2010, for considering the references supplied with the Information Disclosure Statement filed February 25, 2011, and for providing Applicants with initialed copies of the PTO-SB08 forms filed therewith.

Issue under 35 U.S.C. § 103(a)

Claims 12, 14, 15, 17, 21, 22, 26, 30 and 31 stand rejected under 35 U.S.C. §103(a) as being obvious over Bijlsma in combination with De La Torre et al. (Riviste Italiana Di Nutrizone Parenterale Ed Enterale, Vol. 21, No. 3, pp 105-111, Wichig Editore, Milano, IT, January 1, 2003). This rejection is respectfully traversed.

The Present Invention

The present invention is directed to a method for ameliorating or treating an inflammatory bowel disease (IBD), comprising administering a composition comprising galactomannan in an amount sufficient to lower the activity of myeloperoxidase and TNF-α to a patient suffering from said IBD, wherein said galactomannan is a degraded galactomannan having an average molecular weight of from 8,000 to 50,000 and a viscosity of 10 mPa·s or less,

as determined by 0.5 (w/v)% aqueous solution of the degraded galactomannan, wherein the degraded galactomannan is produced by hydrolyzing guar gum with β-mannanase without further chemical processing, and wherein the administering step includes administering the composition having 5-100% by weight of galactomannan in an amount of 1 to 70g/day/adult.

Distinctions Over the Cited Art

As recited in claim 12, the present composition requires at least a specific degraded galactomannan which has an average molecular weight of from 8,000 to 50,000 and a viscosity of 10 mPa·s or less, as determined by 0.5(w/v)% aqueous solution of the degraded galactomannan, and is produced by hydrolyzing guar gum with β-mannanase without further chemical processing.

In contrast, Bijlsma discloses slightly negatively charged non-digestible polysaccharides. As shown in Example 1 of Bijlsma, hydrolyzed guar gum is subjected to further modification by addition of pyridine sulphur trioxide. In Bijlsma, such further chemical modification is carried out for more effectively reducing transport via the tight junctions of the intestines. As illustrated in Fig. 2 of Bijlsma, carboxydextrans effectively inhibit permeability in comparison with neutral dextrans. As such, Bijlsma's polysaccharide is obtained by chemical modification and is distinguishable from the degraded galactomannan without further chemical processing of present claim 12 which further emphasizes this distinction.

With regard to this point, the Examiner asserts in the Advisory Action that

> Applicants contends that the degraded galactomannan encompassed by the present claims is produced by hydrolyzing guar gum with beta-mannase while Bijlsman discloses in Example 1 subjecting guar gum to the treatment with pyridine sulphur trioxide. This argument has not been found persuasive because Applicants has not provided any evidence that the compound produced by the reference's process is materially different from compound encompassed by the present claims.

From the above assertion, it appears that the Examiner does not give any weight to the recitation of "the degraded galactomannan is produced by hydrolyzing guar gum with β-mannanase without further chemical processing." With regard to this point, Applicants respectfully request the Examiner to reconsider this recitation. Specifically, although the

recitation of "wherein the degraded galactomannan is produced by hydrolyzing guar gum with β-mannanase without further chemical processing" is arguably a product-by-process format, patentable weight must be given to such recitation. According to MPEP § 2113, "[T]he structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 162 USPQ 221, 223 (CCPA 1979)". As mentioned above, there are structural distinctions (ionic charges) between the inventive product and the product of the cited art. Therefore, the claimed product-by-process recitation defining the degraded galactomannan for composition for ameliorating or treating an inflammatory bowel disease is a patentable distinction.

Also, the present method is further defined by adding the recitation of "the composition having 5-100% by weight of galactomannan is administered in an amount of 1 to 70g/day/adult." However, Bijlsma fails to teach or suggest administering a composition that comprises from 5 to 100% by weight of galactomannan in an amount of 1 to 70g/day/adult, thereby exhibiting excellent effects for ameliorating or treating an inflammatory bowel disease (see the Tables of the specification).

Further, the secondary reference of De La Torre discloses a partially hydrolyzed guar gum (PHGG). However, the molecular weight and viscosity thereof are not taught by De La Torre. Thus, even if the cited references were to hypothetically be combined with each other, they still cannot achieve the present invention.

Nevertheless, the Examiner notes at page 3 of the Final Office Action that

> "It would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the claimed invention to use partially hydrolyzed guar gum disclosed by De La Torre in the method disclosed by Bijlsma, because partially hydrolyzed guar gum in the absence of further chemical modification was known to be useful for treating IBD as disclosed by De La Torre, i.e., the results obtained by such substitution would have been expected."

Applicants respectfully disagree.

The slightly negatively charged non-digestible polysaccharides of Bijlsma reduce the uptake of high molecular weight substances, allergens and microorganisms through the intestinal wall. In particular, Bijlsma relates to reduction of the free transport of such substances through the tight junctions of the intestines, without the transport of low molecular weight substances. That is, the method of Bijlsma discloses that transport via the tight junctions of the intestines is effectively reduced by further chemical modification, while polysaccharides without chemical modification have no effect (see Fig. 2 of Bijlsma). This clearly teaches away from a combination of the PHGG of De La Torre without any chemical modification. In other words, a skilled artisan would not combine Bijlsma with De La Torre. And, even if combined, there would be no expectation of success since Bijlsma teaches inferior results occur with polysaccharides without chemical modification.

Further, even if Bijlsma with De La Torre would be combined, these cited references individually or in combination fail to teach or suggest using a specific degraded galactomannan having a molecular weight of 8,000-50,000 in an amount sufficient to lower the activity of myeloperoxidase and TNF-α, and also fail to teach or suggest the composition having 5-100% by weight of galactomannan is administered in an amount of 1 to 70g/day/adult.

For the reasons set forth above, reconsideration and withdrawal of the obviousness rejection are respectfully requested.

Conclusion

In view of the above remarks, Applicants believe the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Craig A. McRobbie, Registration No. 42874, at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized in this, concurrent, and future replies to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

Dated: May 13, 2011

Respectfully submitted,

By GARTH M. DAHLEN USPTO #43,575

Craig A. McRobbie
Registration No.: 42874
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road, Suite 100 East
P.O. Box 747
Falls Church, VA 22040-0747
703-205-8000